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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,571	07/25/2003	Usha Kasid	223316	4233

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EXAMINER
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ASHEN, JON BENJAMIN

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/627,571	Applicant(s) KASID ET AL.	
	Examiner Jon B. Ashen	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2005.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,6-8,10,13,14,16-20 and 43-84 is/are pending in the application.  
4a) Of the above claim(s) 13,14,16-20 and 43-61 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1,6-8,10 and 62-84 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/23/2005</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of Application/Amendment/Claims***

1. Claims 1, 6-8, 10, 13-14, 16-20, 43-84 are pending in this application. Claims 2-7 were cancelled by Applicant in the response filed 2/23/2006. Claims 13-14, 16-20 and 43-61 were withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention there being no allowable generic or linking claim in the Action mailed 08/23/2005.

Applicant's response filed 2/23/2006 has been fully considered. Rejections and/or objections not reiterated from the previous office action mailed 08/23/2005 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Information Disclosure Statement***

2. The information disclosure statements (IDS) submitted on 11/23/2005 is compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has are being considered by the examiner. However, reference OK, Chin et al., has not been considered for the following reasons. As stated by Applicant (remarks, pg. 9), reviewing this reference to assess whether it could possibly be relevant to the applicant is a nearly impossible task and also that Applicant has no independent

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understanding that any of the information contained in this document (CD filed with the IDS of 5/31/2005 as an artifact) is material to the patentability of the present application and that it is not available as prior art. Therefore, absent any good and sufficient reasons why consideration of this reference, which according to Applicant, is a nearly impossible task and does not contain information that is material to the patentability of the present application, should be made, it has been placed in the Application file, but the information thereon has not been considered.

3. Claims 1, 6-8 and 10 remain rejected and claims 62-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is drawn to an isolated nucleic acid molecule comprising "a polynucleotide encoding 8 to 180 contiguous amino acids from about 1 to 188 of SEQ ID NO: 2." However, the skilled artisan cannot determine the metes and bounds of what is being claimed because an isolated nucleic acid molecule that comprises a polynucleotide encoding 8 amino acids cannot also be a polynucleotide encoding from about 1 to 188 of SEQ ID NO: 2. How can a polynucleotide that codes for 8 contiguous amino acids code from 1 (amino acid) of SEQ ID NO: 2, for example? The claim language "amino acids from about 1 to about 188 of SEQ ID NO:2", does not limit this amino acid to a range of amino acids of SEQ ID NO: 2, but is reasonably considered to require only that the polynucleotide encode 1 amino acid. Claim 6 is rejected for the same reasons as claim 1 and claims 7-8, 10 and 62-84 are rejected due to their dependence on a rejected base

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claim. In the event that Applicant intends to claim a particular range of amino acids of SEQ ID NO: 2, inclusion of a particular reference to the amino acid sequence contained in SEQ ID NO: 2, would be remedial.

4. Claims 6 and 62-74 are rejected and claims 62-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 recites, "said polypeptide has an amino acid sequence selected from the group consisting of ..... c) the polynucleotide complement of the polynucleotide of a or b. However, the skilled artisan cannot determine the metes and bounds of what is being claimed because the polynucleotide complement of the polynucleotide of a or b polypeptide that has an amino acid sequence, for example.

5. Claims 65-73 and 75-83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to an isolated nucleic acid molecule of claim 1 or claim 6 which "consists of between" 12 and 40 nucleotides or 13 to 40 nucleotides (claims 65-66, 75-76) or which "consists of at least" 14, 15, 16, 17, 18, 19, 20 or 30 nucleotides. However, the skilled artisan cannot determine the metes and bounds of what is being claimed with this terminology, without assumption, because "consists of" is closed language and the polynucleotides of claim 1 and 6, including the polynucleotide complements of a and b in both claims 1 and 6, must be at

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least 24 nucleotides in length, in order to encode a minimum of 8 contiguous amino acids, as required. The skilled artisan cannot envision the scope of the claimed isolated nucleic acid that comprises a polynucleotide that consists of 12 - 20 nucleotides as claimed, that encodes 8 amino acids or that is the complement of a polynucleotide that encodes 8 amino acids, for example.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 6-8 and 10 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 1 has been amended to recite, "An isolated nucleic acid molecule comprising a polynucleotide selected from the group consisting of a polynucleotide encoding 8 to 180 contiguous amino acids from about 1 to about 188 of SEQ ID NO: 2; ....". Applicant has pointed to paragraph 0038 of the specification as filed as providing support for the introduction of the limitation requiring a polynucleotide that encodes 8 to 180 contiguous amino acids of SEQ ID NO: 2. However, section 0038 of the specification as filed discusses polypeptide fragments of the invention, not polynucleotides as claimed. If Applicant believes that support for the claim limitation

above is provided by the specification as filed, Applicant should point out, with particularity, where such support is to be found, for example, and how, for example, the instant disclosure of polypeptide fragments provides support for the claimed isolated polynucleotide molecule.

8. Claims 6 remains rejected and claims 62-84 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record, as set forth in the Action mailed 8/23/2005.

Claim 6 continues to read broadly on a vast genus of polynucleotides that encode any polypeptide that, except for at least 1 conservative amino acid substitution, addition or deletion, which can be any conservative amino acid substitution, addition or deletion, will encode 8 to 180 contiguous amino acids from about 1 or about 2 to about 188 of SEQ ID NO: 2 or any complement thereof. However, the specification as filed does not provide an adequate written description of the broad genus of polynucleotides claimed that can be any polynucleotide that encodes 8 contiguous amino acids that will encode about 1 or about 2 to about 188 of SEQ ID NO: 2 or one that can be that polynucleotide except for at least 1 conservative amino acid substitution, addition or deletion. The skilled artisan cannot immediately envision that Applicant was in possession of this broadly claimed genus.

The specification as filed provides only a general disclosure of what is known in the art of coding nucleic acids, in regard to how one of skill in the art would recognize what amino acid substitutions, additions or deletions would be conservative, generally,

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in polypeptides. However, the specification provides no description of how the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention, that would, for example, lead the skilled artisan to the structure of a polynucleotide that encodes a polypeptide as claimed in a and b of claim 6, or the complement thereof,, wherein except for at least 1 conservative amino acid substitution, addition or deletion, which could be any conservative amino acid substitution, addition or deletion, the polynucleotide will encode 8 to 180 contiguous amino acids from about 1 or about 2 to about 188 of SEQ ID NO: 2.

Additionally, the specification as filed does not disclose any distinguishing identifying characteristics of the claimed polynucleotides that encode polypeptides which, except for at least 1 conservative amino acid substitution, addition or deletion, which can be any conservative amino acid substitution, addition or deletion, the polynucleotide will encode 8 to 180 amino acids from about 1 or about 2 to about 188 of SEQ ID NO: 2. The general description and examples provided by the specification are insufficient to indicate possession of the broadly claimed genera of polynucleotide as claimed. The specification does not provide a disclosure of sufficiently detailed, relevant identifying characteristics that would be required to reasonably lead one of skill in the art to the instant invention or that would allow the skilled artisan to recognize that Applicant was in possession of the instant invention, commensurate with what is now claimed and state of the art cannot provide this description because it is silent on what



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possible "at least 1 conservative amino acid substitution, addition or deletion" could be made to a polynucleotide that encodes 8 contiguous amino acids that are 1 amino acid for example

MPEP § 2163[R-2] I. states:

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., > Moba, B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); < Vas-Cath, Inc. v. Mahurkar, 935 F.2d at 1563, 19 USPQ2d at 1116.

The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., Vas-Cath, Inc., 935 F.2d at 1563-64, 19 USPQ2d at 1117.

Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406; Amgen, Inc. v. Chugai Pharmaceutical, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").

An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. > Enzo Biochem, 323 F.3d at 964, 63 USPQ2d at 1613.<

In the instant case, Applicant has not provided adequate written description of their invention because the specification does not convey, with reasonable clarity to those of skill in the art, as of the filing date sought, that applicant was in possession of the invention now claimed. Applicant has not shown how the invention was "ready for patenting." such as by the disclosure of a polynucleotide that encoded a polypeptide wherein, except for at least 1 conservative amino acid substitution, addition or deletion, which can be any conservative amino acid substitution, addition or deletion, the

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polynucleotide will encode 8 to 180 contiguous amino acids from about 1 or about 2 to about 188 of SEQ ID NO: 2. Neither has Applicant described any distinguishing identifying characteristics sufficient to show that the applicant was in possession of the broad genus of polynucleotides, as claimed.

### ***Response to Arguments***

9. Applicant's arguments filed 2/23/2006 have been fully considered but they are not persuasive. Applicant has stated that, "The claims as amended clearly point out the invention with the required specificity, thus the basis for the objections appears to be moot. Accordingly, the section 112 objections should be withdrawn" (pg. 11). However, in the instant case, there are no objections over section 112 outstanding in the Application and Applicant has presented no traversal of the outstanding grounds of rejection as set forth in the Action mailed 08/23/2005.

### ***Claim Rejections - 35 USC § 102-maintained***

10. Claims 1, 7-8 and 10 remain rejected and claims under 35 U.S.C. 102(b) as being anticipated by Kumar et al. 2000 (Reference BB on PTO Form 1449 filed 7/25/03 in this Application) for the reasons of record as set forth in the Action mailed 08/23/2005.

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11. Claims 1 and 6 remain rejected under 35 U.S.C. 102(b) as being anticipated by Patel et al. 1997 (Reference BK on PTO Form 1449 filed 7/25/03 in this Application) for the reasons of record as set forth in the Action mailed 08/23/2005.

12. Claims 1 and 7-8 remain rejected under 35 U.S.C. 102(b) as being anticipated by Horrevoets et al. (Reference AQ on PTO Form 1449 filed 7/25/03 in this Application) for the reasons of record as set forth in the Action mailed 08/23/2005.

13. Claims 1, 6 and 8 remain rejected under 35 U.S.C. 102(b) as being anticipated by Lamerdin et al. 1998 (Direct submission: AC005339) for the reasons of record as set forth in the action mailed 08/23/2005.

***Response to Arguments***

14. Applicant's arguments filed 2/23/2006 have been fully considered but they are not persuasive. Applicant has argued that none of the prior art references cited (Kumar et al., Patel et al. or Horrevoets et al. discloses the specific sequences recited in the claims as amended. However, contrary to Applicants position, the claims as amended require an isolated nucleic acid molecule comprises a polynucleotide that encodes 8 to 180 contiguous amino acids from about 1 to about 188 of SEQ ID NO: 2. Kumar et al, Patel et al. and Horrevoets et al. each disclose polynucleotides that encodes all amino acids from 1 to 188 of instant SEQ ID NO: 2, for example. Lamerdin et al. disclose a polynucleotide that comprises at least 13 contiguous amino acids of SEQ ID NO: 2, for example (see "pg. 41, sequence alignment attached to Action mailed 08/23/2005).

***Claim Rejections - 35 USC § 102-withdrawn***

15. The rejection of claims 1, 6-8 under 35 U.S.C. 102(b) as being anticipated by Goltsev et al. 1997 (Journal of Biological Chemistry, Vol. 272 (32): 19641-19644) is withdrawn in view of Applicant's amendments to the instant claims.

***Conclusion***

16. No claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon B. Ashen whose telephone number is 571-272-2913. The examiner can normally be reached on Monday - Friday, 7:30 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4715. The fax phone number for the organization where this application or proceeding is assigned is 703-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Jba

  
JANE ZARA, PH.D.  
PRIMARY EXAMINER

TC1600